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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,234	04/06/2001	Tac-Shin Park	0136/OJ067	3081
7278	7590	03/31/2005	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			TUNG, JOYCE	
			ART UNIT	PAPER NUMBER
			1637	
DATE MAILED: 03/31/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/807,234	PARK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 December 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 12-25,27-29 and 31-38 is/are pending in the application.
- 4a) Of the above claim(s) 12-24 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 25, 27-29 AND 31-38 is/are rejected.
- 7) Claim(s) 36-38 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

The amendment filed 12/03/2004 to the Office action has been entered. Claims 12-25, 27-29, 31-38 are pending. Claims 25, 27-29, and 31-38 are under examination.

1. The rejection of claims 25-35 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.
2. Regarding the restriction requirement, the response argues that the present invention is not attempting to claim the individual, disparate HPV nucleic acids. To the contrary, the instant invention is to have an array of HPV strains which a sample DNA can be evaluated for hybridization and therefore, restricting the array of a single probe would essentially defeat the purpose of the instant invention. As stated in the Office action mailed 4/01/04, each of the probes and primer pair bind to different regions of HPV DNA, and therefore, represents distinct products. In addition, since the claim language is unclear whether or not there is one probe or two or eighteen probes on the array, the restriction requirement is made final.
3. Claims 25, 28 and 30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gravitt et al. (J. Clin. Microbiol. 1998, vol. 36(10) pg. 3020-3027), in view of the Stratagene Catalog, 1988).

The response argues that Gravitt et al. do not teach a solid-surface DNA chip. However the limitation "DNA chip" is read in light of the specification. The limitations regarding the definition of the chip have to be in the claims. The rejection is maintained.

4. Claim 29 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Gravitt et al. (J. Clin. Microbiol. 1998, vol. 36(10) pg. 3020-3027), in view of the Stratagene Catalog,

1988), as applied to claims 25, 28 and 30 above and further in view of PCT international application WO 95/22626.

Regarding the definition of DNA chip, the response argues that Gravitt et al. do not teach a solid-surface DNA chip. As discussed above, the limitation “DNA chip” is read in light of the specification. The limitations regarding the definition of the chip have to be in the claims. The rejection is maintained.

5. Claim 27 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Gravitt et al. (J. Clin. Microbiol., 1998, vol. 36(10) pg. 3020-3027), in view of the Stratagene Catalog, 1988), as applied to claims 25, 28 and 30 above, and further in view of Bevan et al. (Biochem J., 1990, Vol. 267(1), pg. 119-123).

The response argues that absent teachings of a DNA chip, Bevan et al. do not supply the requisite suggestion to modify the teachings of Gravity et al. As discussed above, the limitation “DNA chip” is read in light of the specification. The limitations regarding the definition of the chip have to be in the claims. The rejection is maintained.

6. Claim 31 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Gravitt et al. (J. Clin. Microbiol., 1998, vol. 36(10) pg. 3020-3027), in view of the Stratagene Catalog, 1988), as applied to claims 25, 28 and 30 above, and further in view of Sena et al. (5,273,881).

The response argues that Sena et al. do not disclose the streptavidin-fluorochrome conjugate is attached to a DNA chip. The limitation, “DNA chip” is read in light of the specification, but the limitation regarding the definition of the chip has to be in the claims. The rejection is maintained.

7. Claims 32-35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gravitt et al. (J. Clin. Microbiol., 1998, vol. 36(10) pg. 3020-3027), in view of the Stratagene Catalog, 1988), as applied to claims 25, 28 and 30 above, and further in view of published U.S. patent application 2003/001295 to Shalon (“Shalon”).

The response argues that the microarrays (DNA chips) of Shalon et al. is to achieve gene expression profiling, but not to detect the presence of HPV strains. Shalon et al. teach that the chip can be used in genotyping and diagnostic assays and provides the advantages of assaying a plurality of samples simultaneously, is easy to use and provides a highly sensitive detection (See paragraphs, 40, 64,69 and 96, for example). Thus, one of ordinary skill in the art would have been motivated to use the microarray as a chip in the hybridization method of Gravitt. In addition, the limitation, “DNA chip” is read in light of the specification, but the limitation regarding the definition of the chip is not in the claims. The rejection is maintained.

8. Claims 32-33 and 35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gravitt et al. (J. Clin. Microbiol., 1998, vol. 36(10) pg. 3020-3027), in view of the Stratagene Catalog, 1988), as applied to claims 25, 28 and 30 above, and further in view of Zammatteo et al. (Analytical biochemistry, 2000, Vol. 280, pg. 143-150).

The response argues that there is no teaching in Zammatteo et al. of arrays comprising HPV DNA probes or use for the diagnosis of HPV. However, based on the teachings of Zammatteo et al., Zammatteo et al. teach the method of producing microarray is advantageous because the aminated DNA is directly bound without the help of a coupling agent, which provides a more efficient assay (See pg. 145 and 149). Thus, one of ordinary skill in the art

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would have been motivated to use in the hybridization method of Gravitt. The rejection is maintained.

***Claim Objections***

9. Claims 25, 27-29, 31-38 are objected because the claims 25, 27-29 and 31-35 amended add SEQ ID NO: 2-19 which was not elected in Applicants' response, filed on December 16, 2003 in which Applicants' elected Group III, claims 25-35 and SEQ ID NO: 1 and 24-25 and the newly added claims 36-38 also have non-elected SEQ ID NO: 2-19.

***Summary***

10. No claims are allowable.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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12. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782 on Monday-Friday from 10:00 AM-6:00 PM.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using 571 273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

*J-TW*  
March 25, 2005

*Kenneth R. Horlick*  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

3/28/05